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REPORT

Study Title:

Accelerated Storage Stability of K32

Ricerca Study Number: 035236
Ricerca Document Number: 035236-1

Data Requirement:

OPPTS 830.6313 Stability to Normal and Elevated Temperature, Metals, and Metal Ions (August 1996)

Author(s):
Penny Miner
Melissa Grcar

Study Completion Date:
December 07, 2016

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STATEMENT OF NO DATA CONFIDENTIALITY CLAIM

No claim of confidentiality is made for any information contained in this study on the basis of its falling within the scope of FIFRA § 10 (d) (1) (A), (B), or (C).

Company: Koch Agronomic Services

Company Agent: Eric A. Searer

Title: Product Regulatory Manager

Eric A. Searer
Signature

12/7/2016
Date

These data are the property of Koch Agronomic Services, LLC, and, as such, are considered confidential for all purposes other than compliance with FIFRA Section 10. Submission of these data in compliance with FIFRA does not constitute a waiver of any right to confidentiality that may exist under any other statute or in any other country.

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COMPLIANCE STATEMENT

The study reported herein, "Accelerated Storage Stability of K32" Ricerca Biosciences, LLC Study Number 035236, was conducted and reported in compliance with the Good Laboratory Practice Regulations set forth in Title 40, Part 160 of the Code of Federal Regulations of the United States of America.

Penny Miner — December 7, 2016

Penny Miner, Study Director
AgChem Product Development
Ricerca Biosciences, LLC

Date

Eric Searcy — 12/7/2016

Eric Searcy, Sponsor Representative
Koch Agronomic Services, LLC

Date

Eric Searcy — 12/7/2016

Submitter

Date

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QUALITY ASSURANCE STATEMENT

The Ricerca Quality Assurance Unit has performed inspections on the study, "Accelerated Storage Stability of K32," Ricerca Study 035236. The results of these inspections, including any findings or observations, were reported to the Study Director and Management for appropriate corrective actions on the dates listed below:

Phase Inspected	Date of Inspection	Dates Reported to the Study Director	Dates Reported to Management
Protocol	September 1, 2016	September 1, 2016	September 1, 2016
In-Study	October 5, 2016	October 5, 2016	October 5, 2016
Data/Report	November 29, 2016	November 30, 2016	November 30, 2016

Stephen Rogenthien, RQAP-GLP
Ricerca Biosciences Quality Assurance

12/7/16
Date

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APPROVALS

Study Title: Accelerated Storage Stability of K32

Document Number: 035236-1

Testing Facility: Ricerca Biosciences, LLC
AgChem Product Development
7528 Auburn Road
Concord, OH 44077

Penny Miner — December 7, 2016

Penny Miner, Study Director
Ricerca Biosciences, LLC
Date

Phillip Cassidy — December 7, 2016

Phillip Cassidy, Management
Ricerca Biosciences, LLC
Date

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CONDUCT OF STUDY

The purpose of this study was to determine the stability of the test substance, K32, at an elevated temperature. This study was conducted under GLP to meet EPA FIFRA data requirements of guideline OPPTS 830.6313 (Stability to Normal and Elevated Temperature, Metals, and Metal Ions).

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Email: penny.miner@ricerca.com

SCHEDULE OF EVENTS

Study Initiation Date: September 12, 2016
Experimental Start Date: September 21, 2016
Experimental Termination Date: October 7, 2016

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RETENTION OF DATA

All original data (including electronic data), or authenticated copies thereof, and a copy of the final report will be retained using appropriate storage media in the archives of Ricerca Biosciences, LLC upon completion of the study. The Sponsor will be contacted later to determine whether any of the data should be returned, retained or destroyed on their behalf.

SAMPLE RECEIPT AND PREPARATION

The K32 (lot 55700-30-13) was manufactured at Ricerca Biosciences on July 20, 2016.

The following are the significant days in this study:

9/21/2016 (Day 0)
10/5/2016 (Day 14)

Temperatures were monitored continuously over the 14 day interval. Temperature alarm limits were set to 52 °C for the lower limit and 56 °C for the upper limit.

MATERIALS AND METHODS

The test substance is the test system. The study determined the stability at an elevated temperature for K32.

TEST SUBSTANCE

Test Substance Name:	K32
Composition:	Reaction products of NBPT with urea and formaldehyde
Batch/Lot Number:	55700-30-13
Analyzed Concentration:	Reaction product mixtures 80.3 wt%, NBPT 17.3 wt%, water 2.4 wt%
Manufactured by:	Ricerca Biosciences
Date of manufacture:	July 20, 2016
Appearance:	Off-white to pale yellow gel

STABILITY TO NORMAL AND ELEVATED TEMPERATURE PROCEDURE

The K32 storage container was opened and 10 g was placed into each of four 30 mL glass containers. Duplicate glass containers were placed in incubator HQ-INCU-00008 which was set to 54 ± 2 ^{o}C. The other two glass containers were stored at ambient temperature for the duration of the study. When analyzed, approximately 0.2 g of K32 samples were weighed into 4 mL vials and dissolved in acetonitrile/water, 3:7, v:v.

Stability was determined by comparison of the control samples to the elevated temperature samples. An aliquot of approximately 0.2 g from the duplicate glass bottles stored in the 54 °C incubator and 0.2 g of the test material stored in the glass bottles at ambient temperature was used for analysis. The aliquots were taken after the glass bottles had cooled to ambient temperature. Each test sample was weighed into individual tared 4 mL vials, and weights were

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recorded. The samples were diluted using acetonitrile/water, 3:7, v:v and shaken to ensure complete dissolution. Stability was determined by comparative analysis of HPLC profile of the heat treated test substance to the control sample.

HIGH-PERFORMANCE LIQUID CHROMATOGRAPHY (HPLC)

The following LC-UV method was used:

Perkin Elmer™ Series 200 Pump quaternary gradient liquid chromatograph
Perkin Elmer™ Series 200 UV/VIS Detector
Perkin Elmer™ Series 200 LC Autosampler
Radiomatic FLO-ONE®\Beta Model 150TR radioactive flow detector
(all from Perkin Elmer Instruments, Norwalk, CT)

Column: Restek Ultra C18, 3 µm, 150 mm x 4.6 mm
Mobile Phase A: Water
Mobile Phase B: Acetonitrile
Flow Rate: 1.0 mL/minute
Wavelength: 214 nm

Gradient Table 1:

Time (minutes)	Flow Rate	%A	%B
Initial	1.0	87	13
8	1.0	87	13
30	1.0	30	70
31	1.0	87	13
43	1.0	87	13

Total Time: 43 minutes
Injection Volume: 15µL

Data collection by Perkin Elmer Totalchrom™ (a validated system).

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RESULTS

The components tracked as part of the study are as follows:

Component	Retention Time (minutes)
#1, Component 1 (C1)	6.3
#2, Component 2 (C2)	6.8
#3, Component 3 (C3)	9.8
#4, Component 4 (C4)	10.4
#5, Component 5 (C5)	11.4
#6, Component 6 (C6)	27.6
#7, Component 7 (C7)	27.9

None of the components of K32 Formulation were stable over the 14 days of storage at approximately 54 °C. Component C1, C2, C6 increased while the remaining components (C3, C4 and C5) decreased.

At day 14 for the control samples, the average peak area percentage by HPLC of each component was determined to be 2.0%, 5.3%, 2.4%, 24.9%, 53.5%, 5.9% and 6.0% for C1, C2, C3, C4, C5, C6 and C7 respectively. At 14 days for the heat-treated samples, the average peak area percentage of each component was determined to be 0.7%, 1.8%, 3.4%, 30.5%, 57.9% 2.8% and 3.0% for C1, C2, C3, C4, C5, C6 and C7 respectively. Calculations of these results are contained in Table 1 and Table 2. Example chromatograms are available in Figure A through Figure D.

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Figure A: Chromatogram of the K32 Control Formulation at Day 14, Rep 1

Run: 07_oct_2016\uv_002-20161007

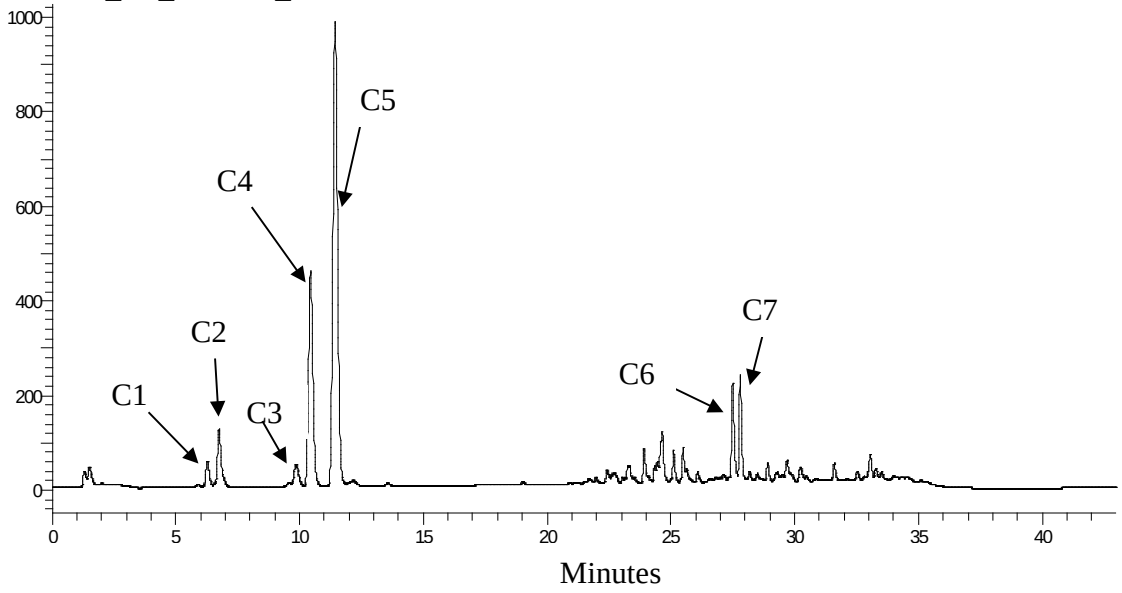

Figure B: Chromatogram of the K32 Control Formulation at Day 14, Rep 2

Run: 07_oct_16\uv_003-20161007

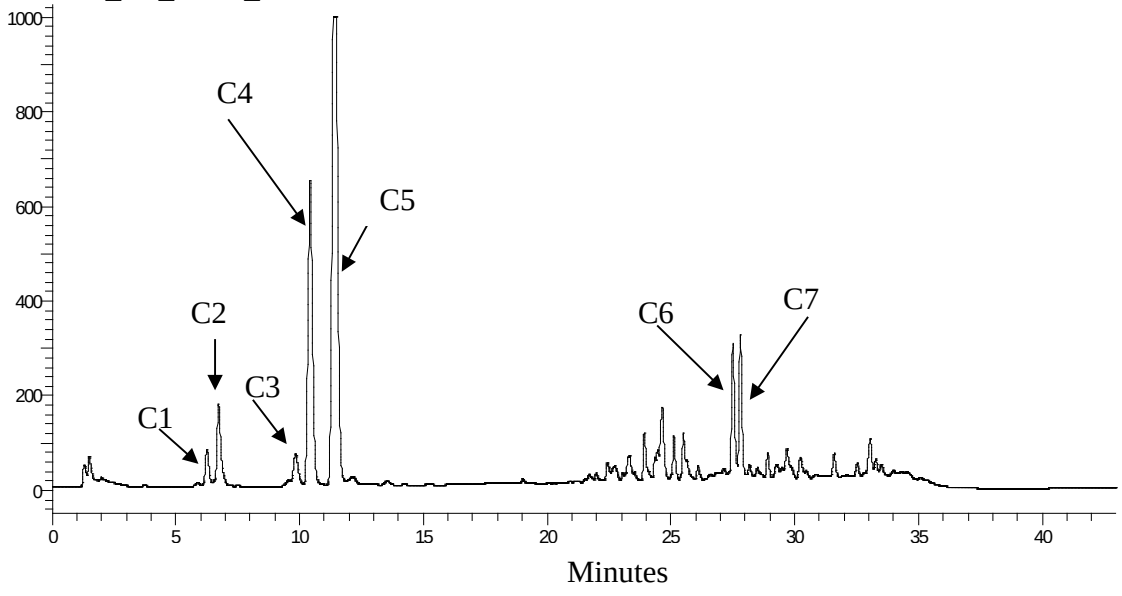

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Figure C: Chromatogram of the Heat Treated K32 Formulation at Day 14, Rep 1

Run: 07_oct_16\uv_004-20161007

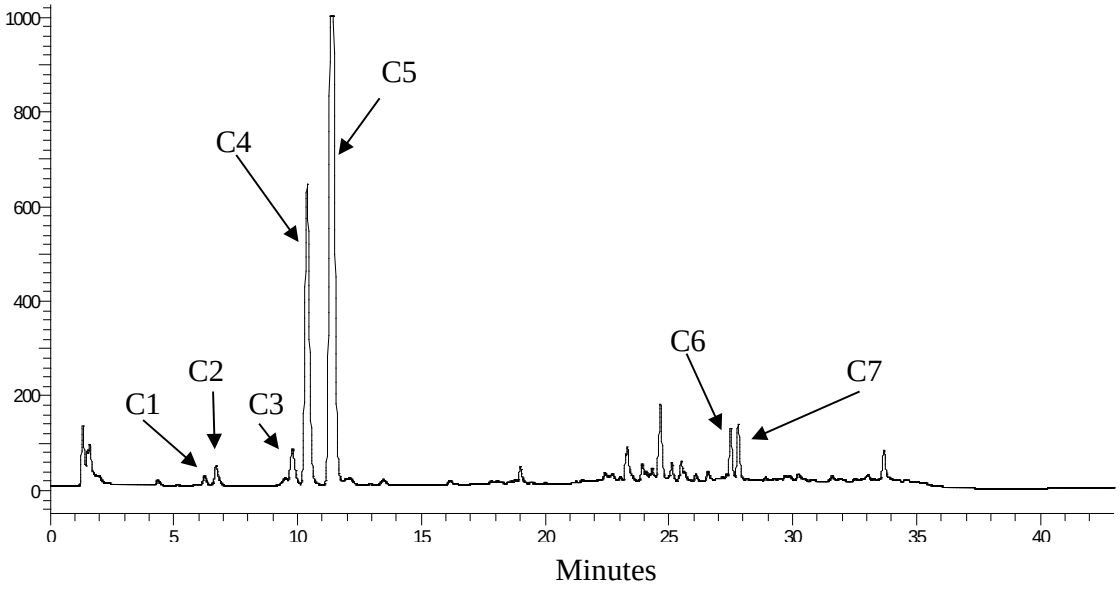

Figure D: Chromatogram of the Heat Treated K32 Formulation at Day 14, Rep 2

Run: 07_oct_16\uv_005-20161007

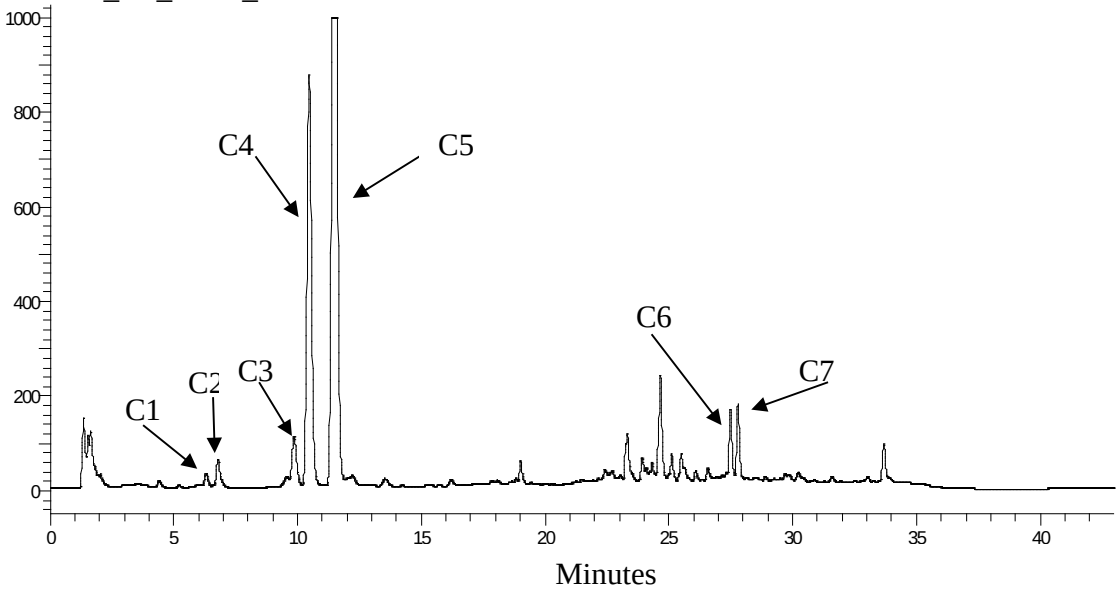

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Table 1: Results from the Analysis of the K32 at Day 14 (Ambient)

	Peak Area % by HPLC*		
	Rep 1	**Rep 2**	**Average**
#1, Component 1 (C1)	1.96	2.01	1.99
#2, Component 2 (C2)	5.15	5.50	5.33
#3, Component 3 (C3)	2.18	2.65	2.42
#4, Component 4 (C4)	23.96	25.81	24.89
#5, Component 5 (C5)	55.28	51.61	53.45
#6, Component 6 (C6)	5.72	6.10	5.91
#7, Component 7 (C7)	5.76	6.32	6.04

**Based on Total peak area*

Table 2: Results from the Analysis of the K32 at Day 14 (54 ± 2° C)

	Peak Area % by HPLC*		
	Rep 1	**Rep 2**	**Average**
#1, Component 1 (C1)	0.58	0.85	0.72
#2, Component 2 (C2)	1.52	1.97	1.75
#3, Component 3 (C3)	2.99	3.76	3.38
#4, Component 4 (C4)	28.82	32.20	30.51
#5, Component 5 (C5)	60.55	55.16	57.86
#6, Component 6 (C6)	2.62	2.92	2.77
#7, Component 7 (C7)	2.92	3.13	3.03

**Based on Total peak area*

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APPENDIX A

Protocol

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Ricerca means Research

PROTOCOL

Study Title:

Accelerated Storage Stability of K32

Document Number: 035236-0

Data Requirements:

OPPTS 830.6313 Stability to Normal and Elevated Temperature, Metals, and Metal Ions (August 1996)

Testing Facility:
AgChem Product Development
Ricerca Biosciences, LLC
7528 Auburn Road
Concord OH 44077

Study Sponsor:
Koch Agronomic Services, LLC
2883 Miller Road
Decatur GA 30035

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INTRODUCTION

K32 is a fertilizer.

PURPOSE

The purpose of this study is to determine the stability at an elevated temperature for K32. The study will be conducted to meet the data requirements of guideline OPPTS 830.6313 (Stability to Normal and Elevated Temperature, Metals and Metal Ions).

EXPERIMENTAL INFORMATION

SCHEDULE OF EVENTS

Proposed Experimental Starting Date: September 2016
Proposed Experimental Termination Date: September 2016

The actual starting and termination dates will be documented in the final report.

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MATERIALS AND METHODS

STORAGE, DISTRIBUTION, AND RETENTION

The test substance will be supplied by the Sponsor or their representative and will be stored at conditions specified by the Sponsor. The original container will be retained until the final report is issued and then discarded. Ricerca Biosciences will dispose of the unused test substance at the completion of the work, unless directed otherwise in writing from the Sponsor.

TEST SUBSTANCE

- **K32**

Composition:	Reaction products of NBPT with urea and formaldehyde
Batch/Lot Number:	55700-30-13
Analyzed Concentration:	Reaction product mixtures 80.3 wt%, NBPT 17.3 wt%, water 2.4 wt%
Manufactured by:	Ricerca Biosciences
Date of manufacture:	July 20, 2016
Appearance:	Off-white to pale yellow gel
Storage:	Refrigerated

CHARACTERIZATION OF THE TEST SUBSTANCE

It is the responsibility of the Sponsor to provide characterization of the test substance used in this study. The Sponsor will assume the responsibility of retention of a sample of the test substance as specified in 40 CFR 160.195.

JUSTIFICATION FOR SELECTION OF TEST SYSTEM

The test procedures have been selected to comply with United States Environmental Protection Agency Product Properties Test Guidelines, August 1996. The test system is the test substance itself.

EXPERIMENTAL DESIGN

Summary of tests to be performed are as follows:

Stability at an elevated temperature will be determined by HPLC. All HPLC data will be collected by Perkin Elmer Totalchrom™ (validated system). Microsoft Excel™ (non-validated software) may be used as to generate necessary statistics.

OVERVIEW

The following detail is provided as a guideline for the conduct of the study. Good scientific judgment may be applied to optimize the experimental results. The actual procedure will be recorded in the data and summarized in the final report.

All standard operating procedures pertaining to this study shall be available for inspection at Ricerca.

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Stability at an Elevated Temperature

Equipment

- Constant temperature chamber
- General laboratory equipment: beakers, flasks, pipets, vials, glassware, etc.
- Liquid chromatographic system equipped with an autosampler, a UV/VIS detector, and a data acquisition system.

Reagents

- Acetonitrile, Methanol or organic solvent specified by the sponsor, HPLC grade or better
- Water, HPLC grade or better

Stability Storage of Sample at a Temperature of 54 ± 2 °C Procedure

1. Place a recorded and measured amount of test substance into each of two separate glass containers. The samples will be placed each in an oven at 54 ± 2 °C for 14 days.
2. Record the date and time the test substance is placed in the oven. Monitor and record oven temperatures during the test period.
3. After the 14-day test period, remove the test substance from the oven and allow to cool to room temperature. The samples will then be submitted for the appropriate testing.
4. Perform HPLC assays on both the heat-treated test substances and a control sample. The control sample will be untreated material, prepared as above, that has been stored at ambient temperature (~25 °C).
5. Compare analysis based on peak area response values for the heat-treated test substance to those from the control sample will determine if any decomposition has occurred.

   Note: If at all possible, assays should be performed within 24 hours.

HPLC/UV Analysis

The stability of K32 heat treated test substances will be compared to the control sample stored at ambient temperature (~25 °C) to determine if any decomposition has occurred by the following HPLC/UV method. Samples should be prepared with 0.2 grams of sample in 1 mL of ACN/water 3:7.

HPLC Method

Column: Restek Ultra C18, 3 µm, 150 mm x 4.6 mm
Mobile Phase A: Water
Mobile Phase B: Acetonitrile
Flow rate: 1 mL/min
Injection volume: 15 µL
Detection: UV, 214 nm

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Gradient Method

Step	Time	MP A	MP B	Curve
0	0.5	87	13	0
1	8.0	87	13	0
2	22.0	30	70	1
3	1.0	87	13	0
4	12.0	87	13	0

Method(s) for Control of Bias

Bias will be controlled in the experiment by use of duplicate samples and by averaging multiple measurements.

Proposed Statistical Method(s)

Appropriate statistical methods for the analysis and evaluation of the experimental data will be used at the discretion of the Study Director. Common statistical methods used to evaluate the precision and accuracy of the measurements may include (as appropriate): average, mean, coefficient of variation, standard deviation, relative standard deviation, and confidence interval. Outlier measurements can be evaluated per standard statistical procedures such as the "t test" or "Q test."

To improve data presentation and interpretation, and facilitate report preparation, the Study Director may apply computer programs for spreadsheets (e.g., Excel), graphics presentations (e.g., PowerPoint), and general standard statistics software.

RECORDS TO BE MAINTAINED

Analysts shall document all experimentation such that an experienced scientist can reconstruct the work. Documentation shall include sample identifications, weighings, dilutions, calculations, etc. Additional documentation shall include instrumentation and equipment utilized during the study, as well as documentation of prepared reagents and solutions.

All study data shall be reviewed or verified and maintained in folders in the study activity file. Other comments, descriptions, calculations, correspondence, etc., shall be placed in the study activity file.

Upon conclusion of the study, copies of representative raw data (as appropriate), shall be submitted to the Sponsor. An accurate study file, including original raw data, shall be submitted to the Ricerca Biosciences, LLC Archives, 7528 Auburn Road, Concord, Ohio.

GLP Compliance

The described study will be conducted in accordance with the U.S. Environmental Protection Agency's "Good Laboratory Practice Standards" as published in 40 CFR Part 160. This study will be routinely examined by Ricerca Biosciences Quality Assurance Unit personnel for compliance of GLP, protocol, and SOPs.

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REPORT

A final report will be prepared at the conclusion of the study. The report shall include, but not necessarily be limited to, the following:

- Name and address of the facility performing the study and the dates on which the study was initiated and completed, terminated, or discontinued
- The approved protocol and any amendments to the original protocol
- Reference(s) to, and/or a detailed description of, all methods used
- Representative data generated while conducting the study, and representative transformations, calculations or operations performed on the data
- Identification of the test substances used in the study
- All deviations and changes from the protocol
- A description of all circumstances that may have affected the quality or integrity of the data
- Name and signature of the Study Director, the names of other scientists or professionals, and the names of supervisory personnel involved in the study
- Statistical methods employed for analyzing the data. A description of the transformations, calculations, or operations performed on the data, a summary and analysis of the data, and a statement of the conclusions drawn from the analysis
- Locations where raw data and the final report are to be stored
- The signed and dated statement by the Ricerca Quality Assurance Unit specifying the dates of study inspections and dates the findings were reported to the Study Director and Management, when applicable
- The signed and dated statement by the Study Director describing compliance with the Good Laboratory Practice Standards as specified in 40 CFR 160

Amendments and Deviations to the Protocol

All agreed upon amendments will be expressed in writing, and signed and dated by the Sponsor and the Study Director. Copies of the signed amendments will be returned to the Study Director and appended to the protocol.

The Study Director will communicate the nature of any deviations to the Sponsor. Deviations from the protocol, if any, will be documented and described in the final report.

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PROTOCOL ACCEPTANCE

Study Title: Accelerated Storage Stability of K32

Document Number: 035236-0

Testing Facility: Ricerca Biosciences, LLC
7528 Auburn Road
Concord, OH 44077

Penny Miner
Penny Miner
Ricerca Biosciences, LLC

September 12, 2016
Date

Phillip Cassidy
Phillip Cassidy, Management
Ricerca Biosciences, LLC

September 12, 2016
Date

Eric C. Searcy
Eric Searcy, Sponsor Representative
Koch Agronomic Services, LLC

9/8/2016
Date

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APPENDIX B

Temperature Record

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Ricerca Environmental Monitoring System (REMS)

Report Type: History Chart
Sensor CMMS Number: HQ-SENB-00260
Department Equipment Name: HQ-INCU-00008
Equipment CMMS Number: HQ-INCU-00008
Equipment Type: Incubator
Building: A
Equipment/Space Location: A-251

Environmental Condition: Temperature
Validated Data: Sensor calibration records on file
Account Code: 02-07
Contact Person: Walsh, Kevin
Report Date:11/17/2016

StartDate:·9/21/2016·12:59:41 PM
EndDate:·10/5/2016·1:00:41 PM
PortionOfDay:·All·Day FillDown:·No